Survey Results for Proposed Stroke and STEMI Regulations
Compiled by Missouri Department of Health and Senior Services
November 2009

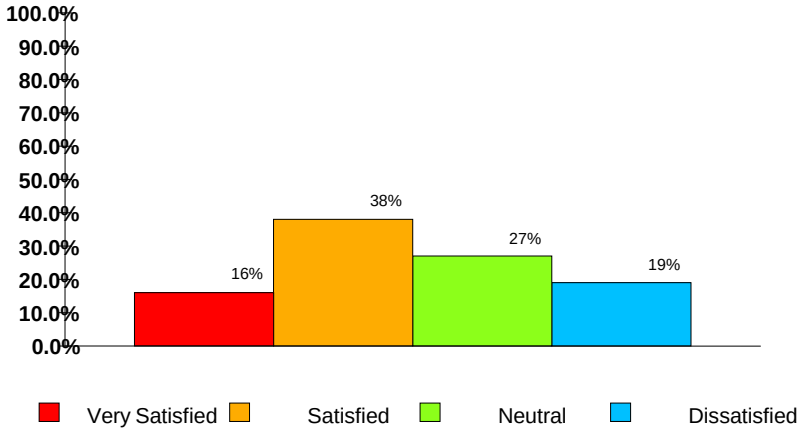
On-Line Survey Time Frame: September 28, 2009 through October 19, 2009

How Promoted:
1. On DHSS website
2. Two emails sent to over 500 people who attended or participated in process
3. Promoted at six regional meetings
4. Partner groups helped promote

Number of Respondents: 42 (33 attended regional meetings)

STROKE REGULATIONS

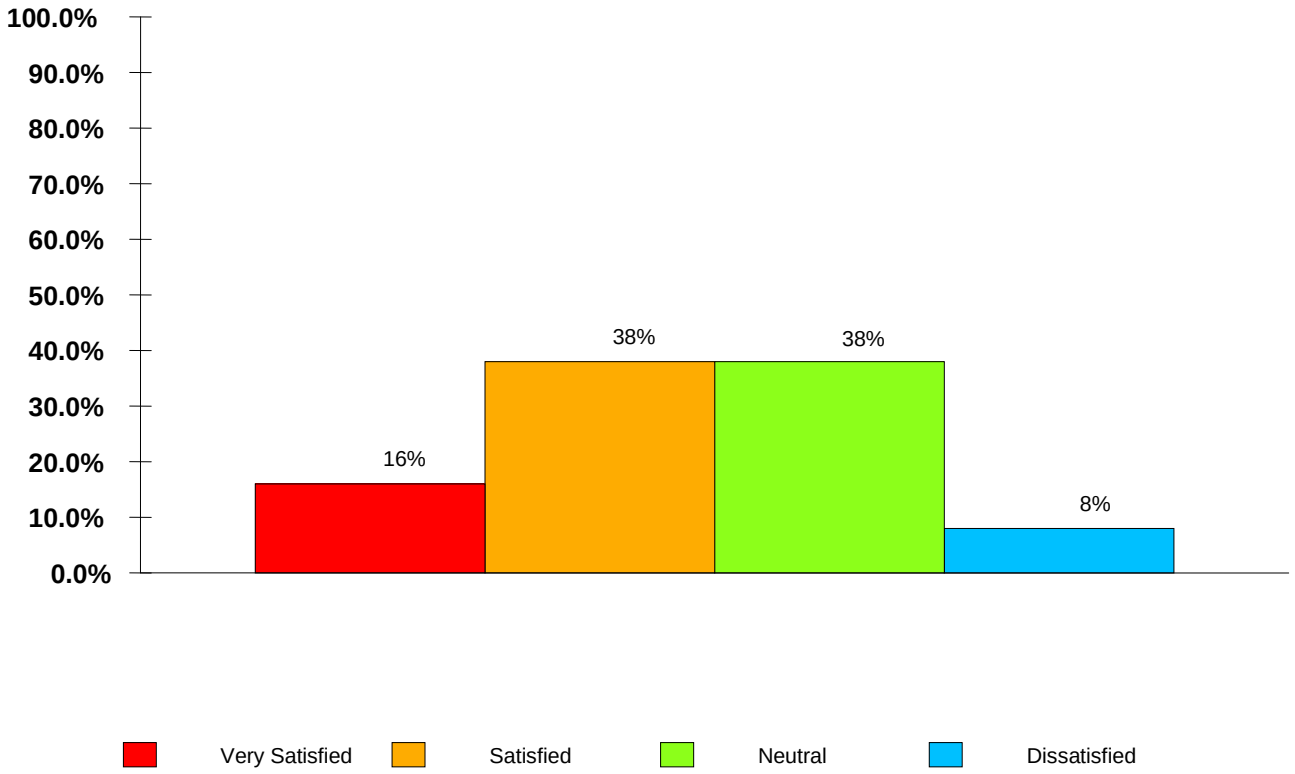
Satisfaction with Section 1 "General Standards for Stroke Center Designation"



Summary of comments-Stroke Section 1-General Standards (8 people commented)

- Three people expressed concern regarding the number of hours of CME and continuing education required. Too costly and this stipulation is not quantified in the Joint Commission (JC) accreditation standards for Primary Stroke Centers (PSC).
- Should not require the Medical Director at Level II to be neurologist since other types of physicians may be qualified for this position.
- Want consistency between these standards and JC standards for PSC. (3 comments)
- The registry should be the same requirements we have for Get with the Guidelines so work is not doubled.
- Consults for physical medicine and rehab should be done within 48 hours, not 24 hours. (CHANGE MADE)
- Requested clarification on stroke patient log requirements.
- The American Heart Association feels that hospital designations within a Stroke System of care should utilize a 2 tiered approach: Primary Stroke Center (PSC) designated facilities, and Non-PSC, Acute Stroke Care Capable (ASC) facilities, in accordance with American Stroke Association recommendations.
- A large group of statewide experts worked for months studying national guidelines and discussing what could work best in Missouri. Thus is a good section.
- There are too many classifications of Stroke Center. The level IV needs to be removed.
- Do not like use of term credentialing for nursing staff.

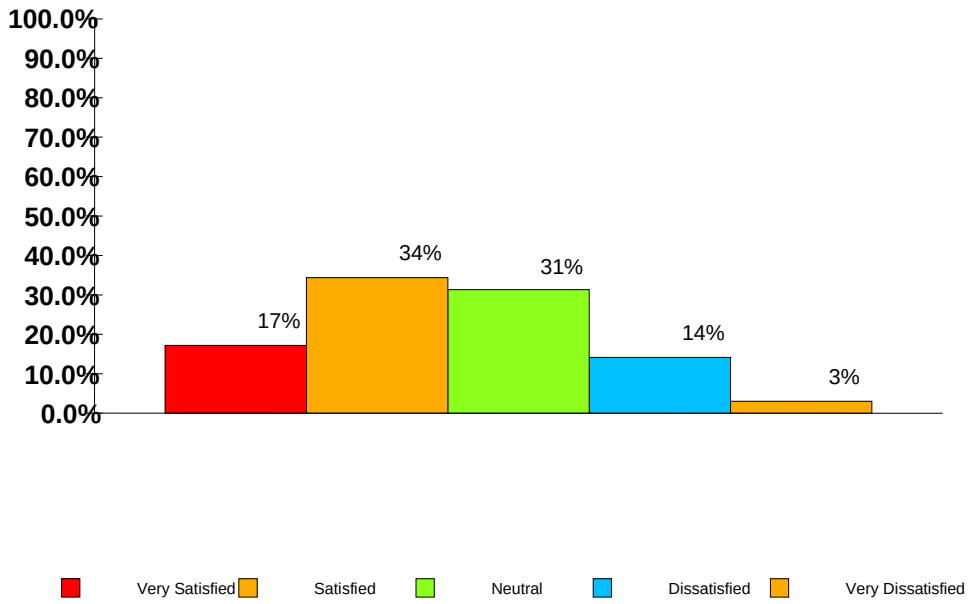
Satisfaction with Section 2 "Medical Staffing Standards for Stroke Center Designation



Summary of comments-Stroke Section 2-Medical Staffing Standards (7 people commented)

- Need clarification between the two descriptions of a neurologist in Section 1 compared to Section 2. The requirement for board certified neurologists is restrictive. Difficult to recruit. Must assure that this level is absolutely necessary to maintain standard of care if another professional certification could also meet best practice standard.
- The need for the neuro-interventional specialist at a level I makes it real hard for any hospital except the large teaching hospitals to be a level I
- CME time requirement too costly for facilities. Too much stroke-specific education required for Level 2 for emergency department physicians and emergency dept. & ICU nurses. Do not like specific details spelled out.
- Content decisions were made by a large group of Missouri clinicians and experts with knowledge of the latest national guidelines and discussions. Content is good.

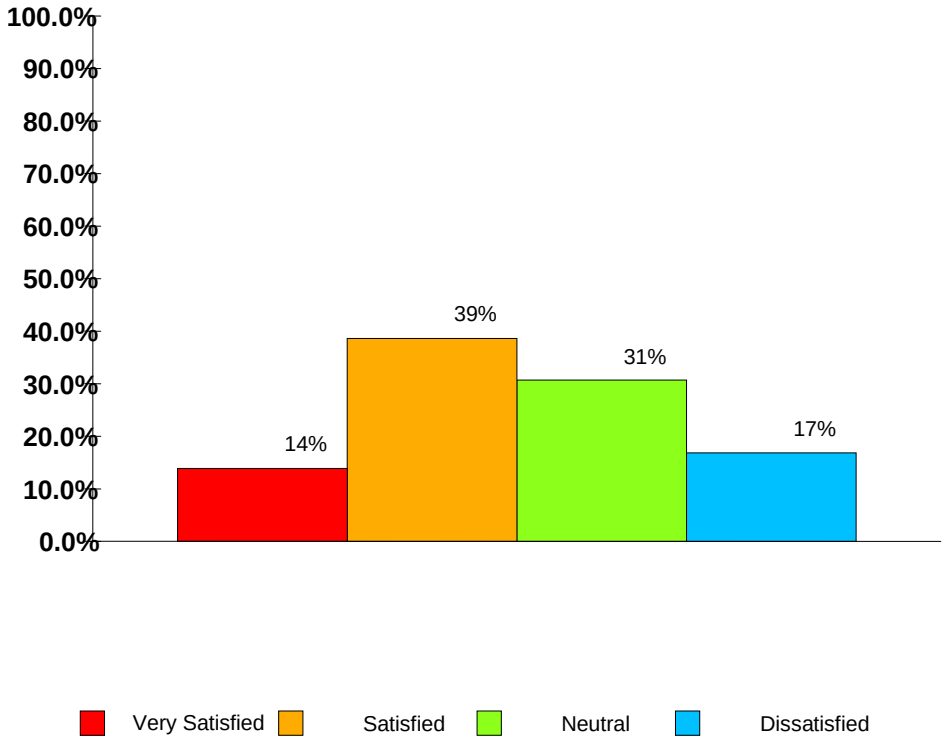
Satisfaction for Section 3:"Standards for Hospital Resource and Capabilities for Stroke Center Designation"



Summary of comments related to Stroke Section 3 –Hospital Resources and Capabilities (9 people commented)

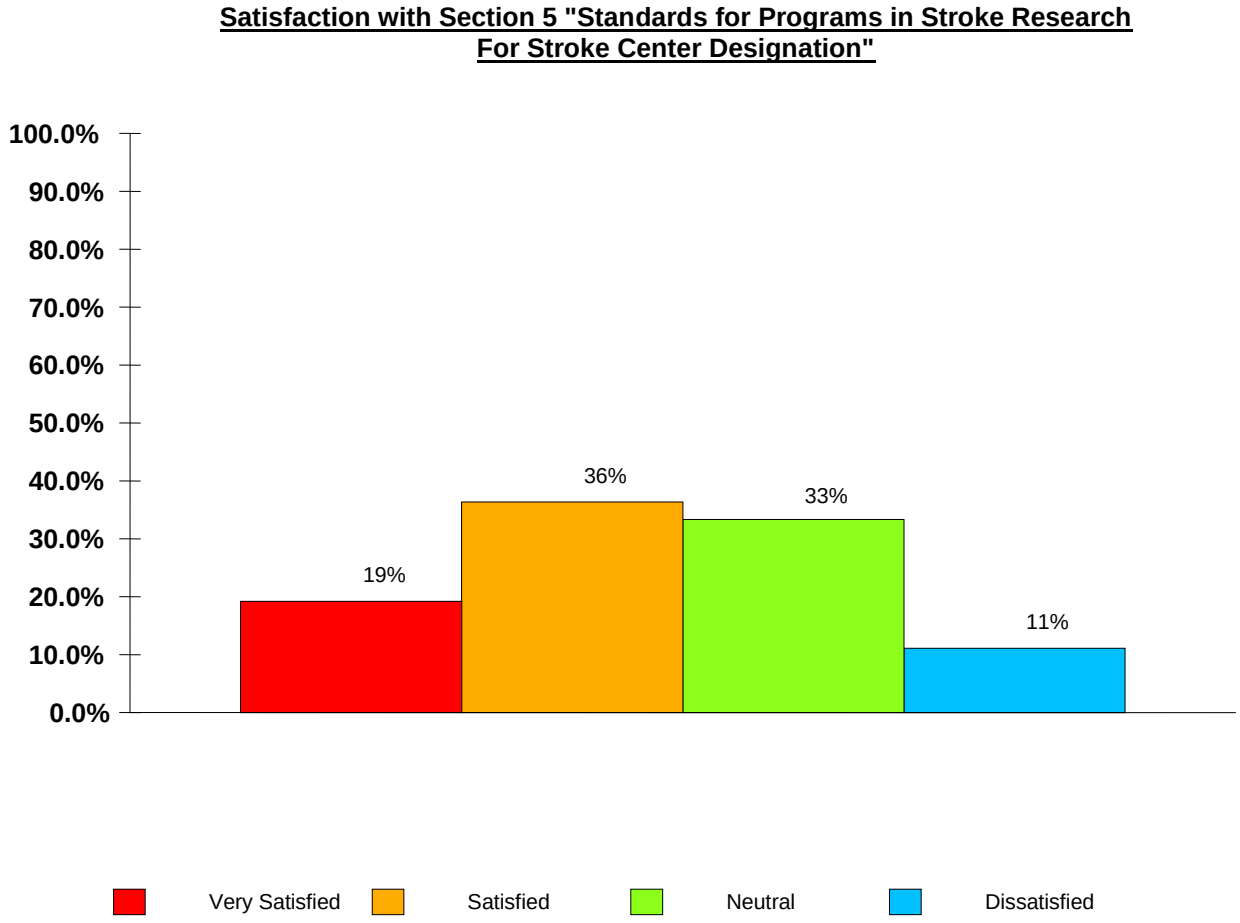
- Too many hours required for continuing education. (5 people)
- Need clarification on policies: 1) defining the relationship between emergency dept. physicians and other physician members off the stroke team and 2) “a physician who is not the emergency dept. physician shall be on duty in the ICU or available 24 hours a day"
- Currently, definitions for standards have been “harmonized” by the Joint Commission, CMS, and the American Heart Association’s (Get with the Guidelines). How will the Missouri registry be aligned with these consensus guidelines? In addition how will we be able to extract data, and maintain the integrity of the analysis of the data if definitions are not consistent? To follow yet another requirement in data reporting speaks to creating additional administrative cost and duplication of effort in a climate where we can ill-afford to further stretch resources.
- Very good work. Using national guidelines as the core, a large group of experts worked for months to draft regulations specifically designed for Missouri.

Satisfaction with Section 4: 'Standard for Hospital Performance Improvement, Patient Safety, Outreach, Public Education and Training Programs for Stroke Center Designation'



Summary of comments related to Stroke Section 4- Standards for Performance Improvement, Patient Safety, Outreach, Public Education and Training Programs (9 people commented)

- Our quality improvement program can capture all these reporting requirements. Want to coordinate so existing data systems can be used and we avoid duplicate data entry to populate state registry. (5 comments)
- The data is very important, we should QA the data. Need to make sure we benchmark on national as well as state level.
- Recommend CT and MR technologists availability stipulations match PSC standards.
- Feedback to EMS within 72 hours is unrealistic. Some patients are still being diagnosed and/or still hospitalized. Feedback is good, though.
- Good work on this section.



Summary of comments related to Stroke Section 5-Stroke Research (4 people commented)

- Too vague. This is too undefined.
- Again there appears to be little recognition in these regulations of other national certification and standards already in place. The restrictive nature has the potential of stifling innovation and creative approaches to patient care. The proposed regulations step over the line in allowing independent judgment to be trumped by a specific practice requirement.
- National recommendations and Missouri expert's discussion are obviously the basis for this well crafted section.

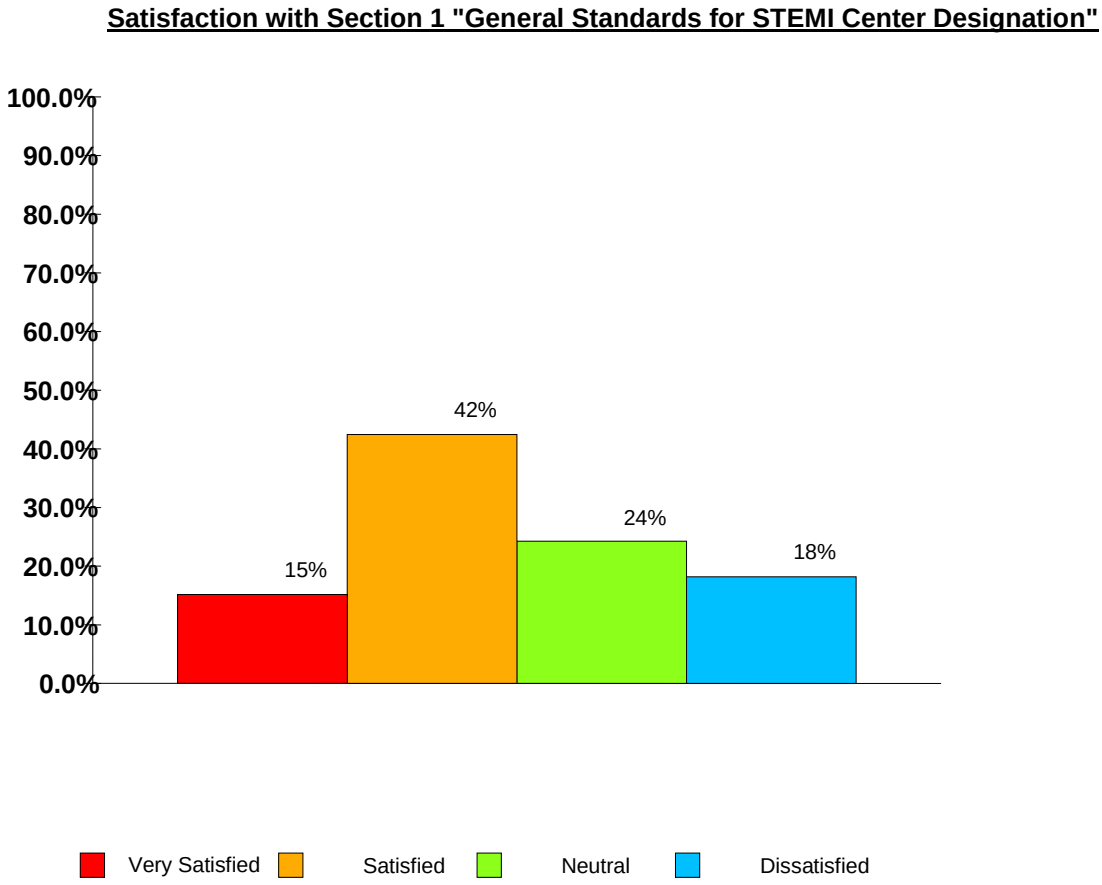
Additional comments on the Stroke Center Designation Regulations (15 people commented):

1. Want alignment of PSC and Level 2 centers.
2. Please make sure that protocols are evidence based and not driven by conflicts of interest from those who have financial stakes in performing interventional procedures. Don't want to divert care away from level two or three centers which are capable of delivering tPA and would be able to do so much earlier in the clinical course. Time is brain and delaying delivery of care should not be acceptable.
3. Great job
4. Throughout this two year process, over 400 experts from around our state participated in all-day meetings. I was there, and I was impressed by their diligent use of national guidelines and recommendations, their discussions about what will work best in Missouri, and their continual focus on a TCD system designed to improve patient outcomes in Missouri. The regulations are an excellent product of the hard work of dedicated professionals volunteering their time to benefit all Missourians.
5. Worthy goals and the structure seems beneficial, the transportation system away from rural areas is not sufficient to support this program outside urban areas. And while it provides options to help rural facilities support the program the costs associated with initiating and maintaining are likely over time to be greater than the benefits provided especially as patients are directed away from these facilities to ones in the metro area.
6. I strongly believe that the legislative intent in the statute was that the local medical director be responsible for creating the applicable time critical diagnosis protocols for their service. It is appropriate for DHSS to develop and reference Time Critical Patient Routing Plans that do not include prescriptive assessment and treatment modalities. I believe that time critical diagnosis protocols should not be referenced in regulation. As the science on time critical diagnosis will likely change over time and further research, referencing the protocols in regulation could result in patients being treated in a manner that does not reflect current treatment recommendations which could place the State of Missouri in a position of liability. Additionally any referenced document could legally carry the weight of regulation, and thereby become mandated rather than guidance only. Guidelines should be general in nature, not specific to a certain medication or treatment modality. New studies are being done daily which may lead us to significantly different conclusions than we currently believe appropriate. State guidelines should establish the minimum standards not the optimal expectations across a state with a mix of urban, suburban and rural communities. (8 comments, Mid America Regional Council for Emergency Response [MARCER] endorsed)
7. I am an EMS person, so I will leave the comments to the hospitals.
8. I have concerns that the proposed changes would mandate statewide protocol on areas that already have a well defined policy regarding these issues. The ability to change protocol as the science changes is extremely important. No protocol for EMS should be implemented by law, but rather through the established system of regional effort and the service Medical Director. The Bureau of EMS can, and should, provide guidelines to be used, but placing specifics in law isn't a good idea.
9. The physician CME requirements need to be balanced between Trauma, Stroke and STEMI.
   There are too many hours of CME for physicians. At a hospital that is a trauma center, stroke center and STEMI center the ED doc would have to have 24 hours per year of CME in these three areas...but this is plain too many!

Comments you have regarding Stroke Definitions (5 people commented, 3 were the same as Number 5 in the above section):

- Provided official definition for Telemedicine from American Telemedicine Association (ATA). (Changed to ATA definition.)
- Well done.

STEMI REGULATIONS

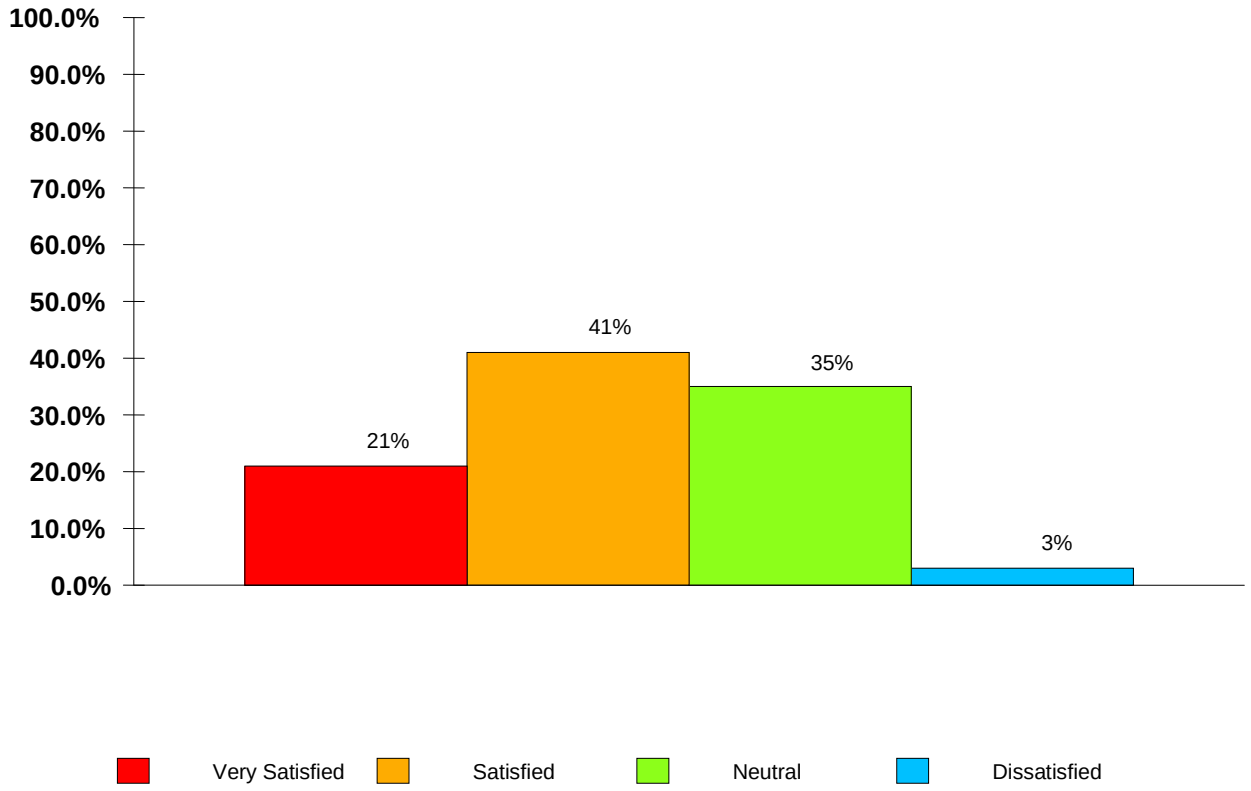


Summary of comments related to STEMI Section 1-General Standards (9 people commented)

- I feel that more emphasis should have been placed on actual outcomes versus the 36 primary PCIs. I feel that the volume rule exception should NOT preclude more than one hospital in a community from achieving the rule exception. I am unclear as to how a hospital that is designated a Level III can ever hope to attain a Level II. Would there be an allowance for an institution that plans to invest heavily in their CV program in order to upgrade?
- The STEMI task force recommended the STEMI centers meet volume requirements, it is unfortunate there was an out given to the level II's. There is also some concern with the term 'near' in a hospital that is near but not at... If exceptions are going to remain for level II's then these same exceptions should apply for level I's.
- The American Heart Association feels that hospital designations within a STEMI System of Care should utilize a 2 tiered approach: STEMI receiving (PCI capable) and STEMI referring (not PCI capable), in accordance with AHA Mission: Lifeline Criteria.
- Provided additional extensive detail regarding care standards, e.g., primary PCI availability in receiving hospital, cardiac catheterization lab stipulations, and competence standards for interventional cardiologists.
- As with the Stroke Regulations, the degree of minutia begins to encroach on best practice judgment by skilled practitioners.
- Well done. Draft accomplished by much open large group discussion and study of national recommendations.
- There are too many classifications of STEMI Center. The level IV needs to be removed. In reality all facilities have the capability to refer patients to those facilities with enhanced capabilities. Excessive division complicates decision making schemes.
- Need to drop the expectation from 95% in (1)(F)3.F to 75% to match ACC guidelines/recommendations.
- Level I institutions need procedures in place to institute therapeutic hypothermia.

- Credentialing is mainly used for Physicians and would require a new system set up for the credentialing of nursing staff. The hours of required "yearly" education for all the staff members caring for the TCD patients can be a burden on the hospitals.

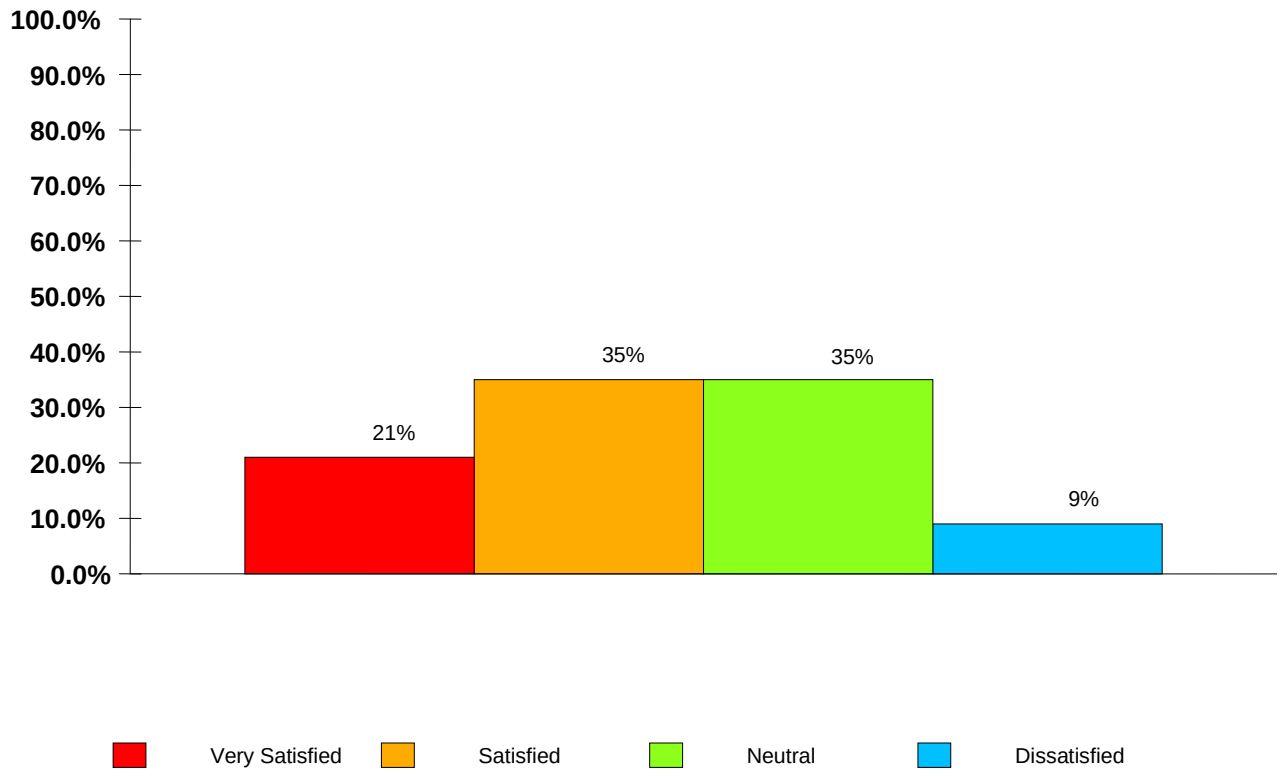
Satisfaction with Section 2 "Medical Staffing Standards for STEMI Center Designation



Summary of comments related to STEMI Section 2-Medical Staffing Standards (5 people commented)

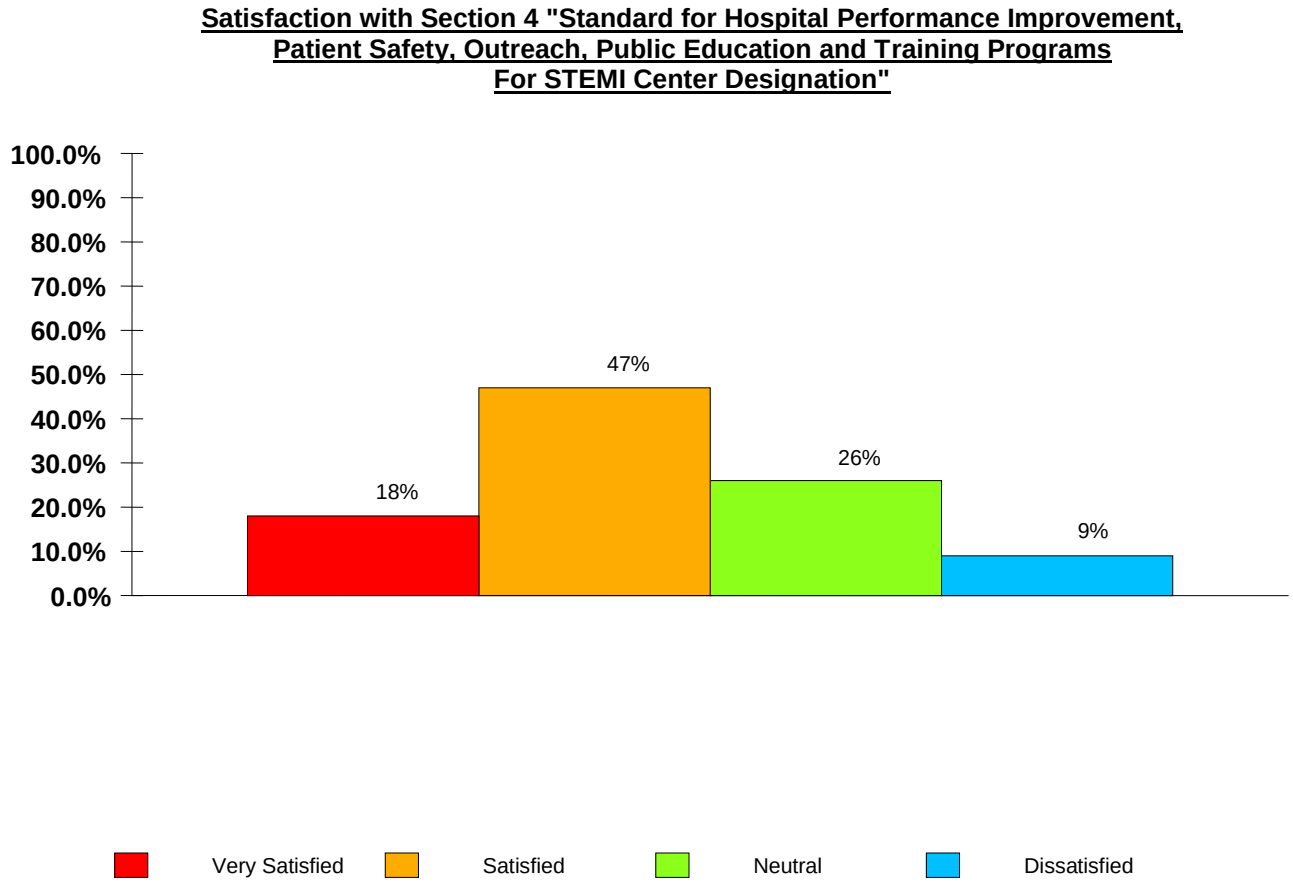
- CME time requirement too costly for facilities
- Too much focus on cardiology and not enough on emergency medicine - that appears to be very much subordinate to cardiology instead of being co-directors (without ED buy in this will not work)
- Regulations once again appear to be too restrictive in their personnel requirements. Requiring a board certified interventional cardiologist versus a cardiologist raises the question about whether this requirement improves best practice and quality of care.
- Good work. Many hours of large group discussion in an open forum focused national recommendations and what could improve patient outcomes in Missouri. Well-done section.

Satisfaction with Section 3 "Standards for Hospital Resource and Capabilities " For STEMI Center Designation



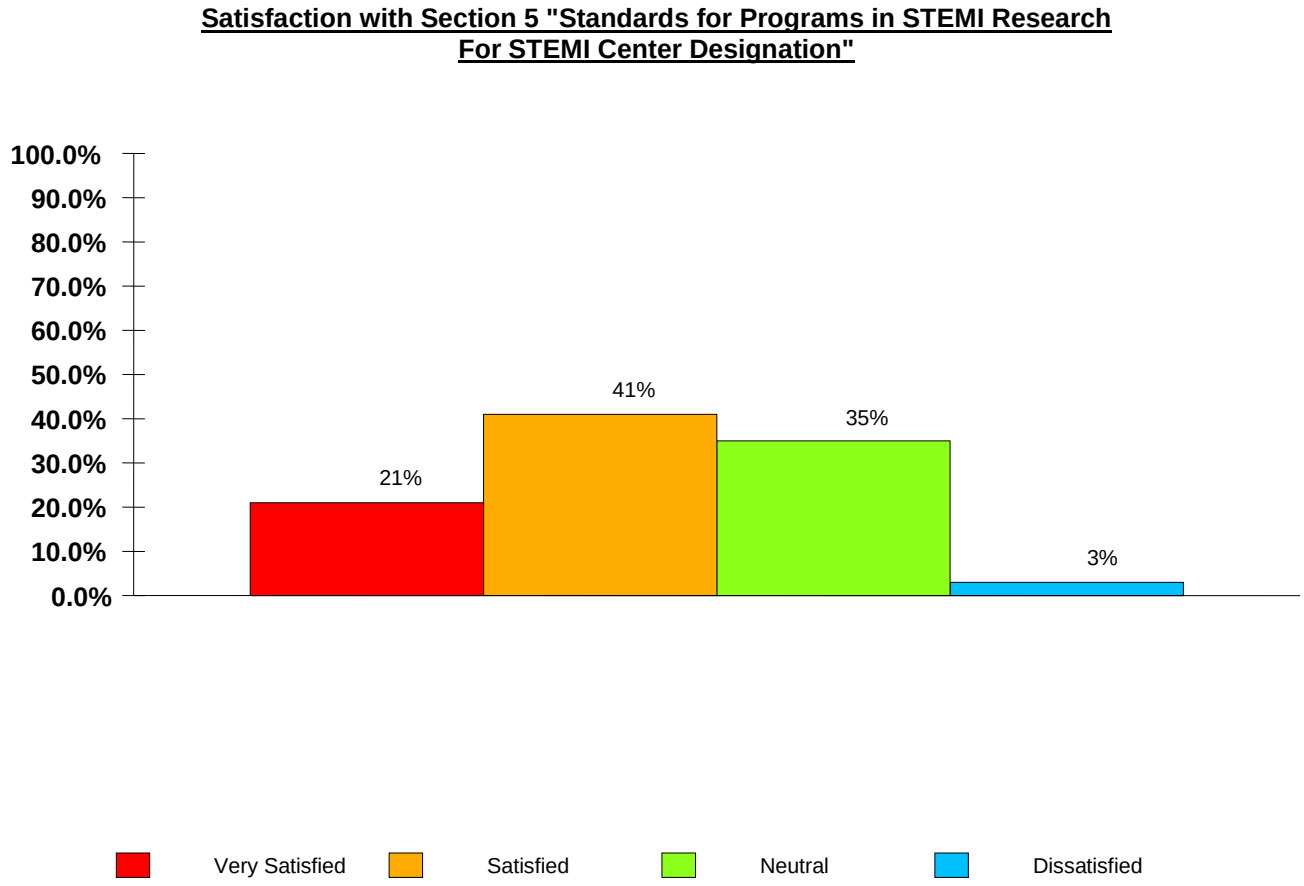
Summary of comments related to STEMI Section 3-Hospital Resources and Capabilities (7 people commented)

- CME time requirement too costly for facilities (2)
- Need to emphasize emergency department capability and cardiology-ED interaction
- The extreme detail throws a barrier in front of those individuals who would and should be able to use independent judgment without sacrificing high standards. Identifying outcomes, evaluation practices and continuous quality improvement, must be part of the regulatory formula.
- Well done.



Summary of comments related to STEMI Section 4- Hospital Performance Improvement, Patient Safety, Outreach, Public Education and Training Programs (4 people commented)

- We recommend Action Registry Get With the Guidelines for the purpose to report data and compare to national guidelines. The national data point measurements are the ones being pushed by the American College of Cardiologist and the American Heart Association
- Coordination and training of community transport personnel and education will be critical in the implementation of these regulations.
- Well done.
- There needs to be a way to use the current data collection process we use (not requiring data to be also placed into the state data base) thus the data could be benchmarked nationally not just in the state of MO



Summary of comments related to STEMI Section 5-STEMI Research (2 comments)

- Well done. Much large group discussion about national recommendations and what would be best for patient care in Missouri.

Additional comments on the STEMI Center Designation Regulations (13 comments)**:**

1. Too much emphasis on PCI only, data still shows that PCI will not be close to universally available despite what cardiologist think (they don't appreciate the logistical barriers to pulling this off)
2. The regulations should be reviewed for balance between overly restrictive regulations and best practice standards. The regulations appear to overlook national certification and best practice standards that are currently in place such as those from the Joint Commission, CMS, AHA and others.
3. This document is the product of many respected clinicians and experts from around the state who volunteered their time to craft the very best TCD STEMI System for Missouri. They continually reminded each other to move away from the siloed interests of their particular modality or employer and to design a system using national guidelines, focusing on what can work in Missouri to improve overall STEMI patient care.
4. The physician CME requirements need to be balanced between Trauma, Stroke and STEMI and not be too many.
5. I believe strongly that the legislative intent in the statute was that the local medical director be responsible for creating the applicable time critical diagnosis protocols for their service and then submit then to the Missouri Bureau of EMS for approval. It is appropriate for the Bureau to provide guidelines to the local medical director pertaining to assessment, triage and transportation. 2. I believe that time critical diagnosis protocols should not be referenced in regulation. As the science on time critical diagnosis will likely change over time and further research, referencing the protocols in regulation could result in patients being treated in a manner that does not reflect current treatment recommendations which could place the State of Missouri in a position of liability. 3. Guidelines

should be general in nature, not specific to a certain medication or treatment modality. As new studies are being done daily which may lead us to significantly different conclusions than we currently believe appropriate. State guidelines should establish the minimum standards but not the optimal expectations across a state with a mix of urban, suburban and rural communities. (7 comments, MARCER endorsed)

Comments regarding STEMI Definitions. (4 comments)

Three were the same as comment number 5 from STEMI additional comment section; the other stated "well done".

Other Information:

Number of TCD meetings attended by respondents:

(N=40)

Number of meetings attended	Number	Percentage
None	5	13%
1-3	19	48%
4-6	4	4%
7 or more	12	30%

Position held by respondent

(N=39)

Positions	Number	Percentage
EMS	12	31%
Hospital Administrator	7	18%
Physician	8	21%
Nurse/Nurse Practitioner	6	15%
Other	6	15%

Number working for a hospital:

(N=40)

Work for a hospital	Number	Percentage
Yes	19	48%
No	21	53%

Responders whose hospital Intends to apply for center designation

(N=20)

Hospital Intends to Apply	Number	Percentage
No	3	15%
Yes	11	55%
Not Sure	6	30%

Stroke Center Designation (N=9)	Number	Percentage	STEMI Center Designation (N=8)	Number	Percentage
Stroke Level I	3	33%	STEMI Level I	3	38%
Stroke Level II	4	44%	STEMI Level II	5	63%
Stroke Level III	1	11%	STEMI Level III	0	
Stroke Level IV	1	11%	STEMI Level IV	0	